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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,073	06/29/2005	Yoshiyuki Ishikura	47237-0561-00 (216942)	4059

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EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,073	ISHIKURA ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-6 and 29-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6 and 29-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 page*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the amendments filed on 07/15/2008 wherein claims 3-6 have been amended, claims 1 and 12-27 have been cancelled and claims 29-33 are newly added.

2. Claims 3-6 and 29-33 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 07/15/2008 regarding the rejection of claims 7-11 and 28 made by the Examiner under 35 USC 112, first paragraph to written description have been fully considered and they are found persuasive. This rejection has been withdrawn.

4. Applicants arguments filed 07/15/2008 regarding the rejection of claims 2-11 and 28 made by the Examiner under 35 USC 112, first paragraph to enablement have been fully considered and they are found persuasive. This rejection has been withdrawn.

5. Applicants arguments filed 07/15/2008 regarding the rejection of claim 3, 5 and 8 made by the Examiner under 35 USC 112, second paragraph as being indefinite have been fully considered and they are found persuasive. This rejection has been overcome by amendment.

6. Applicants arguments filed 07/15/2008 regarding the rejection of claims 2-6, 10, 11 and 28 made by the Examiner under 35 USC 102(b) over Akimoto et al. (US 2004/0266874) have been fully considered and they are found persuasive. This rejection has been overcome by amendment.

New Grounds of Rejections, Necessitated by Amendment
Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. **Claims 4 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Akimoto et al. (US 2004/0266874; of record).**

9. Akimoto teaches a method of administering a composition comprising a triglyceride having arachidonic acid as a constituent fatty acid to ameliorate the diseases caused by decreased brain function such as verbrovascular dementia (see Examples 3 and 4; see instant claim 29). Akimoto teaches that the compound used in their method is obtained from *Mortierella alpine* (see Example 1; see instant claim 4).

10. With respect to the intended use or outcome of the instantly claimed method, no patentable weight is given. It is widely known that a chemical compound and its properties are inseparable. So while Akimoto does not specifically teach that a method of administering a triglyceride with a component arachidonic acid to enhance vascular elasticity, it would necessarily have this property. The disclosed functions of the instant application do no render the method patentably distinct over the art. See MPEP 2111.04.

11. Thus, Akimoto anticipates the instantly rejected claims.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. **Claims 3-6 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akimoto et al. (US 2004/0266874; of record) evidenced Strub (Southern Medical Journal, Volume 96, Number 4, pages 363-366; of record) and Nucleus Medical (http://ebsco.smartimagebase.com/displaymonograph.php?MID=138)**

14. Akimoto is relied upon for disclosure described in the rejection of claims 4, 29 and 30 under 35 U.S.C. 102(e).

15. As noted above, Akimoto teaches that the compositions can be useful for treating cerebrovascular dementia. The definition of cerebrovascular dementia (Strub, "Vascular Dementia," 2003, Southern Medical Journal, Volume 96, Number 4, pages 363-366, Historical Perspective Section) is an arteriosclerotic dementia in which the arteriosclerosis (hardening of the arteries) of the brain would result in a subsequent narrowing of the arteries, resulting in multiple small vessel infarcts that manifest themselves in dementia of the subject (see instant claim 30). Akimoto teaches the compound having arachidonic acid as the constituent fatty acid is an alcohol ester or a triglyceride or a phospholipid (see claim 2). Example 7 teaches the triglyceride in a composition at about 32% by weight (see instant claim 3). Moreover, Akimoto discloses a triglyceride compound having arachidonic acid as a constituent fatty acid as being extracted from multiple microorganisms, such as *Mortierella alpine* (see claim 4 and [0032]).

The location and the identity of the medium-chain fatty acids are also taught by Akimoto. See [0038]) which states that the triglycerides have fatty acids bound at the 1,3-position and arachidonic acid is bound at the 2-position can be from 5 mol % and above, up to 30 mol % (see instant claim 5). Preferred fatty acids have from 6 to 12 carbon atoms (see [0032]; see instant claim 6).

16. Akimoto fails to positively teach a method of administering the compound to an individual having an ischemic cardiac disease such as a myocardial infarction, arteriosclerosis or a cerebral hemorrhage (i.e. stroke).

17. Regardless, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Akimoto with a reasonable expectation for success in arriving at a method of administering a triglyceride having an arachidonic acid component to a person suffering from an ischemic cardiac disease or arteriosclerosis. While Akimoto does not specifically teach the method as being administered to a subject with an ischemic cardiac disease, it would have been obvious to an ordinary skilled artesian to do such because Akimoto states that such compounds possesses utility in treating cerebral dementia which is characterized by arteriosclerosis and minor infarcts in the vessel walls. And although Akimoto does not states that the infarction is an myocardial infarction, this however, does not lend any patentable matter to the instant claims. An infarction is an infarction, regardless of the location of the infarction. Whether it is in a vessel distant from the heart or is actually on the heart itself is immaterial to the final result. With respect to treating a population afflicted with a cerebral hemorrhage, this is obvious. As it is known that cerebral arteriosclerosis leads to hemorrhagic strokes (i.e. cerebral hemorrhage) which can sometimes be fatal (see Nucleus Medical), one of ordinary skill would

expect the administration of arachidonic triglyceride to effectively treat such a condition because, as already noted, the compound is disclosed by the art as useful in treating diseases characterized by arteriosclerosis of cerebral blood vessels. Thus, one would be motivated to administer the compound to an individual with a cerebral hemorrhage because such as a condition, it is characterized by arteriosclerosis formation. Thus, by administering the compounds to such a subject would improve the cerebral blood vessels health and decrease the likelihood that the cerebral hemorrhage will be fatal. Therefore, a method of treating a population characterized by their possessing arteriosclerosis, an ischemic disease or a cerebral hemmorhage with a triglyceride with arachidonic acid component is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

19. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
November 17, 2008

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611